

Community Blood Bank Center

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August 31, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sirs:

At this time I find the recommendations of the FDA to indefinitely defer donors who have spent 6 months, cumulatively, between 1980 and 1996 in the UK to be onerous. The importance of increasing the safety of the blood supply is understood, but I do not believe this measure will increase its safety. Lacking any evidence that nvCJD can be transmitted by blood transfusion, how do we tell the public we can not use their blood, but not to be concerned about their health?

These unwarranted recommendations will unnecessarily increase questions concerning safety of the blood supply, and further reduce the donor pool. There are too many unanswered questions, including differences between CJD and nvCJD. It is unrealistic to use valuable resources to perform a lookback without having any evidence of the disease being transmitted by blood transfusion.

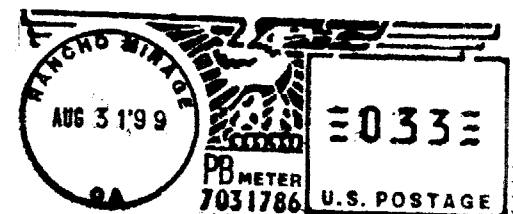
Sincerely,

Donald Rector
Director Quality Assurance

97D-0318

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